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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,099	07/11/2001	Geetha Shankar	10602-013-999	1334

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EXAMINER

ULM, JOHN D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,099

Applicant(s)

SHANKAR ET AL.

Examiner

John D. Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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1) Claims 28 to 44 are pending in the instant application. Claims 1 to 27 have been canceled and claims 28 to 44 have been added as requested by Applicant in the correspondence filed 26 October of 2004.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 October of 2004 has been entered.

5) Claims 29 and 31 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependent claim can not conceivably be infringed without infringing any of the claims from which it depends. Claim 29 can be infringed by a nucleic acid that does not infringe the protein of claim 28. See M.P.E.P. 608.01(n)III.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6) Claims 38 to 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement and under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 38 is incomplete because it only requires the Edg receptor recited therein to comprise one extracellular domain, one transmembrane domain and a chimeric intracellular domain comprising an intracellular loop and a carboxy terminal strand. It is well established in the art, as shown by Figure 1 of the instant application, that Edg receptors are members of the G protein-coupled receptor family. Each and every member of the G protein-coupled receptor family contains four extracellular domains consisting of an amino terminal domain and three extracellular loops, seven transmembrane domains, and four cytoplasmic domains consisting of three intracellular loops and a carboxy terminal. Further, it is unclear how one can have an intracellular loop and a carboxy terminal strand without having at least three transmembrane domains and an extracellular loop. A "loop" is a portion of that receptor that extends beyond a membrane surface and is flanked by two transmembrane domains. This claim is incomplete because it does not recite a sufficient number of structural elements to define an Edg receptor or an intracellular loop thereof. Further, it is not enabled because the instant specification

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does not provide the guidance needed to produce a functional Edg receptor comprising anything less than four extracellular domains, seven transmembrane domains and four cytoplasmic domains.

7) Claims 28 to 37 and 41 to 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 28 is vague and indefinite because the recited elements "Edg 1/3(ct)" and "Edg 8/4(ct)" do not appear to meet the limitation of comprising "a non-contiguous replacement of at least one intracellular domain strand of a first Edg receptor". The text on page 32 of the instant specification indicates that Edg 1/3(ct), for example, is a simple chimera comprising residues 1 to 314 of Edg-1 joined to residues 302 to 378 of Edg-3. There appears to be no "non-contiguous replacement" in Edg 1/3(ct) or Edg 8/4(ct). Claims 29 to 37 and 41 to 44 are vague and indefinite in so far as they depend from claim 28 for this element.

8) Claim 37 is vague and indefinite because the limitation "Gcq protein" is not contained in the specification as filed nor is it defined by the prior art.

9) Claims 28 to 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Ancellin et al. publication (J. BIOL. CHEM. 274(27):18997-19002, 02 Jul. 1999) in view of any two or more of the Conway et al. (J. BIOL. CHEM. 275(27):20602-20609, 07 Jul. 1999), Schöth et al. (MOL. PHARM. 54:154-161, 1998), Wu et al. (J. BIOL. CHEM. 272(14):9037-9042, 04 Apr. 1997), Meng et al. (EUR. J. PHARM. 311:285-292, 1996), Holtmann et al. (J. BIOL. CHEM. 270(24):14394-14398, 16 Jun. 1995), Takagi et al. (J. BIOL. CHEM. 270(17):10072-10078, 28 Apr. 1995), Buggy et al. (J. BIOL. CHEM.

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270(13):7474-7478, 1995), Kim et al. (J. BIOL. CHEM. 269(46):28724-28731, 28 Nov. 1994), Gether et al. (J. BIOL. CHEM. 268(11):7893-7898, 15 Apr. 1993) and Kobilka et al. (SCIENCE 240:1310-1316, 03 Jun. 1988, cited by Applicant) publications for those reasons of record as applied to claims 1 to 27 in the previous office action. As stated therein, the instant claims are drawn to a chimeric Edg receptor comprising domains from Edg1 and Edg3, and an assay employing it. Whereas the elected species of chimeric receptor, Edg 1/3(i3ct), is free of the art, these claims specifically encompass an embodiment recited therein as Edg 1/3(ct), which is obvious in view of the cited combination of references for those reasons of record.

Claim 44 encompasses a configuration that is analogous to the chimeric receptors identified as CH-5 in Figure 2 of the Buggy et al. publication, N91 and 106C in Table I of Kim et al., B(N-III)/A(IV-C) and A(N-III)/B(IV-C) in Figure 2 of Takagi et al., CR NK1 (NK3-TM3-7) in Figure 1 of Gether et al., CCK-B₁₋₂A₃₋₅ in Figure 1B of Wu et al., and CR1 in Figure 1B of Kobilka et al. To have produced this specific embodiment of a chimeric Edg 1/Edg 3 receptor was fairly taught by this combination of references prior to the time of the instant invention.

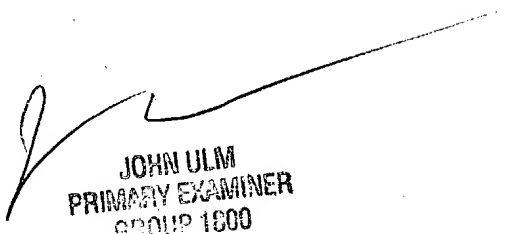
Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brunmbach can be reached on (571) 272-0961. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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